



[Billing Code: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1743-N]

Medicare Program; Meeting Announcement for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the virtual public meeting dates for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) on Wednesday, July 29, 2020 and Thursday, July 30, 2020. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on issues related to clinical diagnostic laboratory tests.

DATES:

Meeting Dates: The virtual meeting of the Panel is scheduled for Wednesday, July 29, 2020 from 8:30 a.m. to 5:00 p.m., Eastern Daylight Time (E.D.T.) and Thursday, July 30, 2020, from 8:30 a.m. to 5:00 p.m., E.D.T. The Panel is also expected to virtually participate in the Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting for Calendar Year (CY) 2021 on June 22, 2020 in order to gather information and ask questions to presenters. Notice of the CLFS Annual Public Meeting for CY 2021 is published elsewhere in this issue of the **Federal Register**.

Deadline Date for Registration: All stand-by speakers for the Panel meeting must register electronically to our Clinical Diagnostic Laboratory Test (CDLT) Panel dedicated email box,

CDLTPanel@cms.hhs.gov. Registration is not required for non-speakers. The public may view this meeting via webinar, or listen-only via teleconference.

Webinar and Teleconference Meeting Information: Teleconference dial-in instructions, and related webinar details will be posted on the meeting agenda, which will be available on the CMS website approximately 2 weeks prior to the meeting at <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>. A preliminary agenda is described in section II of this notice.

ADDRESSES: Due to the current COVID-19 public health emergency, the Panel meeting will be held virtually and will not occur at the campus of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT: Rasheeda Arthur, PhD, (410) 786-3434, e-mail CDLTPanel@cms.hhs.gov. Press inquiries are handled through the CMS Press Office at (202) 690-6145. For additional information on the Panel, please refer to the CMS Web site at <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>.

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) is authorized by section 1834A(f)(1) of the Social Security Act (the Act) (42 U.S.C. 1395m-1), as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93), enacted on April 1, 2014. The Panel is subject to the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels.

Section 1834A(f)(1) of the Act directs the Secretary of the Department of Health and Human Services (the Secretary) to consult with an expert outside advisory panel established by the Secretary, composed of an appropriate selection of individuals with expertise in issues related to clinical diagnostic laboratory tests, which may include the development, validation, performance, and application of such tests. Such individuals may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics.

The Panel will provide input and recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS), on the following:

- The establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use “crosswalking” or “gapfilling” processes to determine payment for a specific new test.
- The factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests.
- Other aspects of the new payment system under section 1834A of the Act.

A notice announcing the establishment of the Panel and soliciting nominations for members was published in the October 27, 2014 **Federal Register** (79 FR 63919 through 63920). In the August 7, 2015 **Federal Register** (80 FR 47491), we announced membership appointments to the Panel along with the first public meeting date for the Panel, which was held on August 26, 2015. Subsequent meetings of the Panel and membership appointments were also announced in the **Federal Register**.

II. Agenda

The Agenda for the July 29 and July 30, 2020 Panel meeting will provide for discussion and comment on the following topics as designated in the Panel's charter:

- Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS) new and reconsidered test codes, which will be posted on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html.
- Other CY 2021 CLFS issues designated in the Panel's charter and further described on our Agenda.

A detailed Agenda will be posted approximately 2 weeks before the meeting, on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>. The Panel will make recommendations to the Secretary and the Administrator of CMS regarding crosswalking and gapfilling for new and reconsidered laboratory tests discussed during the CLFS Annual Public Meeting for CY 2021. The Panel will also provide input on other CY 2021 CLFS issues that are designated in the Panel's charter and specified on the meeting agenda.

III. Meeting Participation

This meeting is open to the public. Stand-by speakers may participate in the meeting via teleconference and webinar. A stand-by speaker is an individual who will speak on behalf of a company or organization if the Panel has any questions during the meeting about technical information described in the public comments or presentation previously submitted or presented by the organization or company at the recent Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting for CY 2021 on June 22, 2020. The public may also view or listen-only to the meeting via teleconference and webinar.

IV. Registration Instructions for Stand-by Speakers

Beginning Friday, May 1, 2020 and ending Wednesday, July 1, 2020 at 5:00 p.m. E.D.T., registration to serve as a stand-by speaker may be completed by sending an email to the following resource box CDLTPanel@cms.hhs.gov. The subject of the email should state “Stand-by Speaker Registration for CDLT Panel Meeting.” In the email, all of the following information must be submitted when registering:

- Stand-by Speaker name.
- Organization or company name.
- E-mail addresses that will be used by the speaker in order to connect to the virtual meeting.
- New or Reconsidered Code (s) for which the company or organization you are representing submitted a comment or presentation.

Registration details may not be revised once they are submitted. If registration details require changes, a new registration entry must be submitted by the date specified in the “DATES” section of this notice. In addition, registration information must reflect individual-

level content and not reflect an organization entry. Also, each individual may only register one person at a time. That is, one individual may not register multiple individuals at the same time.

When registering, individuals must also specify the new or reconsidered test codes on which the company or organization they are representing submitted a comment or presentation. A confirmation email will be sent upon receipt of the registration. The email will provide information to the speaker in preparation for the meeting. Registration is only required for stand-by speakers and must be submitted by the deadline specified in the “DATES” section of this notice. We note that no registration is required for participants who plan to view the Panel meeting via webinar or listen via teleconference.

VI. Panel Recommendations and Discussions

The Panel's recommendations will be posted approximately 2 weeks after the meeting on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>.

VIII. Special Accommodations

Individuals viewing or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should send an email to the resource box (CDLTPanel@cms.hhs.gov). The deadline for submitting this request is listed in the “DATES” section of this notice.

IX. Copies of the Charter

The Secretary's Charter for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests is available on the CMS website at <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html> or you

may obtain a copy of the charter by submitting a request to the contact listed in the “FOR FURTHER INFORMATION CONTACT” section of this notice.

X. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 28, 2020.

Evell J. Barco Holland,

Federal Register Liaison,

Department of Health and Human Services.